REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested. To this end, petition is hereby made for a one-month extension of time to respond to the outstanding Office Action mailed July 29, 2009.

Claims 21-37 and 39 are pending in this application, claims 1-20 and 38 having been withdrawn by the Examiner, and claims 40 and 41 having been previously cancelled. Upon entry of this Amendment, claims 22-24, 37 and 39 will be cancelled and claims 21 and 25 will be amended.

In the outstanding Office Action, the Examiner objected to claim 39 as being dependent on a withdrawn claim, and also rejected claim 39 under 35 U.S.C. §102(b) as being anticipated by Gertzman *et al.* (USP 6,437,018). Given that claim 39 has been cancelled by this Amendment, the Examiner objection to and §102(b) rejection of claim 39 are now moot and should be withdrawn.

In the outstanding Office Action, the Examiner also rejected claims 21, 22, 25, 26, 28, 35, 36, 37 and 39, again under 35 U.S.C. §102(b), as being anticipated by Phillips *et al.* (U.S. Publication No. 2003/0027883), and rejected claims 21-37 and 35 under 35 U.S.C. §103(a) as being unpatentable over Phillips *et al.* in view of Saito *et al.* (EP 0739638) and Benedict *et al.* (USP 6,679,918). The Examiner's rejections are respectfully traversed.

For a claimed invention to be anticipated by a prior art reference, every element of the claim must be disclosed in the reference. For a claimed invention to be obvious over a combination of prior art references, there must be some reason as to why one of

ordinary skill in the art would have sought to combine the references as argued by the Examiner so as to produce the claimed invention.

Here, the claimed invention of the present application is not anticipated by the cited references because such references do not disclose or suggest all of the limitations of the rejected claims. The claimed invention is also not obvious over the cited references because, even assuming, *arguendo*, that the Examiner properly combined the cited references, the resulting combination still would not be the claimed invention given the deficiencies in the teachings of the cited references discussed below.

The present invention is directed to a cost-effective, sterile and user friendly kit for use by medical professionals in the orthopedic environment. The kit is used to prepare and dispense an osteoinductive agent product which includes a plurality of modified naturally occurring biocompatible biopolymers which are selected from the group consisting of collagen, hyaloronic acid, and demineralised bone (DMB), which are first mixed and thereafter subjected, in the solid or dry state, to a source of ionising radiation in the presence of a mediating gas, which is selected from the group consisting of acetylene; ethylene and propylene; and annealed in the absence of oxygen at a temperature of from 40°C to 120°C to render the product in a dry particulate form, the product being disposed in a hermetically sealed container containing oxygen-free gas and radiated again, as now recited in amended independent claim 21 of the present application.

Phillips does NOT disclose such a kit. Phillips is primarily concerned with manufacturing of biopolymers by solid state irradiation in an unsaturated gaseous

atmosphere. Phillips does NOT teach an osteoinductive agent product which includes a plurality of biocompatible biopolymers, which are first mixed and thereafter subjected to a source of ionising radiation.

As Dr. Du Plessis, the named inventor in this application, states in his Rule 132 Declaration submitted with this Amendment, while it is known that radiation is useful for sterilizing products, there are advantages to first mixing and then radiating a product after mixing the biocompatible biopolymers, which include: (a) enhanced cross-linking of the biopolymers; (b) a decrease in production time and costs, eliminating the steps of first radiating the products separately, and thereafter, mixing them and radiating the product again before packaging; and (c) a reduction in the chances for contamination, as a result of radiating the product only after mixing the biocompatible biopolymers.

Dr. Du Plessis also states in his Rule 132 Declaration that radiation is a cold process and is therefore especially applicable to plastics disposables, as it will not distort the plastic, such that, to ensure sterility of the final product, the entire kit (modified naturally occurring biocompatible biopolymer, primary, secondary and tertiary container) is sealed in plastic and radiated again, as is now recited in independent claim 21 of the present application. This step ensures that the product is sterile and ready for use by medical professionals in the orthopedic sterile environment.

The Examiner's reference to the mention in column 27 of Phillips of "tripple packaging" of Demineralized Bone (DMB) and new processed bone (NPB) is NOT an enabling disclosure of an osteoinductive agent product including a mixture of biocompatible biopolymers and processed, as recited in claim 21, and then disposed in a

hermetically sealed container containing oxygen-free gas and radiated again, as also recited in claim 21.

Applicant notes that Benedict is primarily concerned with the manufacture of an implantable putty material, and that, while Benedict mentions the use of kits as a method of delivery of the prepared medicament, Benedict, however, fails to mention that the modified naturally occurring biocompatible biopolymer is first mixed and thereafter subjected, in the solid or dry state, to a source of ionizing radiation in the presence of a mediating gas.

Applicant further notes that Saito describes the sterilization of pre-filled syringes by means of an autoclave, but also fails to describe the process involved of first mixing the ingredients, subjecting the mixture to radiation, packaging of ingredients and then subjecting the kits to radiation for a second time.

As such, Applicant believes that Benedict and Saito do mot compensate for the noted deficiencies in the teachings of Phillips.

In view of the foregoing, it is clear that the amended claims are clearly distinguishable from the prior art documents cited by the Examiner, and, as such, that the cited references do not anticipate or render obvious the claimed invention.

In further support of the non-obviousness of the claimed invention in the current application, Applicant points to the commercial success of the claimed kit of the present application. Specifically, as Dr. Du Plessis further states in his Rule 132 Declaration, since May of 2003, 5250 units of the invention have been sold to the National Tissue Bank of the University of Pretoria and Southern Medical (Pty) Ltd collectively, and that

The Tissue Bank has, since that time, exported 450 units to various foreign countries. Dr. Du Plessis further states that Celtis Medzintechnologie GmbH, an Austrian company, has taken a technology license granting them the exclusive right to manufacture and promote the kits in Europe. Applicant submits, then, that in view of this commercial success, the claimed invention is not obvious in view of the cited references.

Finally, the Examiner rejected claims 21-37 and 39 on the ground of non-statutory, "obviousness-type" double patenting as being unpatentable over claims 1-3, 6-10, 14, 16, 20-22, 25, 28, 36, 37, 43 and 48-50 of Phillips in view of Saito and Benedict, or over claims 1-3, 6-9, 12, 18, 23, 29-32 and 34 of the same combination of references.

A nonstatutory, obviousness-type double patenting rejection requires two or more patents or applications to have at least one common inventor and be either commonly assigned/owned, or if not commonly assigned/owned, then subject to a joint research agreement, as set forth in 35 U.S.C. §103(c)(2) and (3) of the U.S. Patent Statute. MPEP §804(II)(B)(1).

Here, it is believed that the obviousness-type double patenting rejection is misplaced in this application because, although there is a common inventor between this application and the Phillips patent, *i.e.,* Dr. Du Plessis, as Dr. Du Plessis states in his declaration, while he jointly owns this application with Mr. Malan DeVilliers (see Attachments A and B), he has no ownership interest in the Phillips patent and such patent and this application are not subject to a joint research agreement. Indeed, that this application and the Phillips patent are not commonly assigned/owned is evidenced by the USPTO assignment record for the Phillips patent, attached to this Amendment as

Attachment C, which shows that the Phillips patent is currently assigned to San-EI-Gen F.F.I., Inc.

In view of the foregoing, it is now believed that all of the claims pending in the application, *i.e.*, claims 21, 25 – -36 and 39 are now in condition for allowance, which Action is earnestly solicited. If any issues remain in this application, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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